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Dosage adjustments for immunotherapy

1/12/2011

Q. **I have 2 questions regarding adjustment of immunotherapy in patients who are receiving their maintenance dose injections.**

1. How would you adjust the maintenance dose for patients receiving monthly maintenance injections that require a new vial (same manufacturer and allergens, but different lot number)? The latest allergen immunotherapy practice parameter (3rd update, 2010) states that "the physician can consider decreasing the dose by 50% to 90% of the previous dose. For changes in manufacturer and nonstandardized extracts, a greater decrease in dose might be necessary." In your opinion or practice, should the build-up back to the full 0.5 mL maintenance injection be done on a weekly or monthly basis? Would advancing by 0.05 mL at each injection be considered appropriate? And finally, would a 50% reduction in dose be considered aggressive given the wide reduction range (50-90%) and caveat regarding nonstandardized extracts in the practice parameter.

2. My next question has been addressed before however some aspects remain unclear. If a patient is on maintenance immunotherapy and doses are missed, how would you approach resuming the injections? For example, what adjustments would you make for a patient on maintenance who misses, 1, 2, 3, 4, 6, 8, 10, 12, and >12 weeks? The practice parameter primarily addresses missed doses during the build-up phase and that a similar dose reduction protocol should be developed for gaps in maintenance immunotherapy.

I realize there are no true evidence based answers to these questions but your personal expert opinion and experiences regarding these issues would be greatly appreciated.

A. Thank you for your recent inquiry.

It is the custom in our practice for patients receiving monthly injections who require a new vial to decrease the dose by 50 percent and build to maintenance with weekly injections requiring five weeks to return to maintenance level. Thus we would decrease the dose from 0.5 ml to 0.25 ml, and build back by 0.05 increments until 0.5 ml is reached. We then return to monthly injections.

As you stated, there is no evidence-based grounds to make a decision regarding this dose adjustment. It is simply based on the way I was trained. I have continued to utilize this regimen after leaving Fellowship. This is purely a personal way to deal with new vials. It is not an established practice.

I have copied for you below the answer to your Question Number 2. This answer was recently posted on our website. For your convenience, I have copied the response below. As you can see from this response, the guidelines you cite do deal with your Question Number 2 to some extent (Appendix 4). I think that the statement which is copied below should be self-explanatory in this regard. Unfortunately the guidelines do not go beyond a one month delay in injections.

I cannot give you a "cookbook" response regarding my own personal practice in this regard because it is not "cookbook" in nature. It depends upon a number of factors including the antigen(s) administered, the patient's general health status, the disease being treated (asthma versus rhinitis), the original skin test data, et cetera. This is simply a decision, because of a lack of any evidence-based data, that is best made by the physician treating each individual patient since they are most familiar with all of this information.

Thank you again for your inquiry and we hope this response is helpful to you.

Dose adjustments for patients late for allergen immunotherapy injections
1/4/2011
Question: In a patient on maintenance immunotherapy and with no prior adverse reactions to IT, what is the longest, safest interval to continue immunotherapy injections without dropping back completely to the starting dose (ex: a patient coming in for every 4 week IT hasn't been seen in >15 weeks)? Thank you

Response: Thank you for your recent inquiry.

The Parameters on Allergen Immunotherapy (1) is the best source of information to answer your question. I have copied below, for your convenience, their statement regarding dose adjustments for late administration of allergy injections. As you can see there is no established protocol dealing with your question. Unfotunately there are simply no studies offering data to allow such a protocol to be formulated. In the final analysis, as seen in the quote from the Parameter, dosage adjustments for delays greater than one month are made by each individual physician. In my practice, a delay of 12 weeks mandates returning to the first dose.

Thank you again for your inquiry and we hope this response is helpful to you.

Dose adjustments for late injections
Summary: Statement 46: It is customary to reduce the dose of allergen immunotherapy extract when the interval between injections is prolonged. During the build-up phase, it is customary to repeat or even reduce the dose of allergen immunotherapy extract if there has been a substantial time interval between injections. This depends on (1) the concentration of allergen immunotherapy extract that is to be administered, (2) whether there is a previous history of systemic reactions, and (3) the degree of variation from the prescribed interval of time, with longer intervals since the last injection leading to greater reductions in the dose to be administered (see Appendix 4 for an example of a dose-modification regimen for gaps in treatment).

APPENDIX 4. Example of immunotherapy dose adjustments for unscheduled gaps in allergen immunotherapy injection intervals (modification of the AAAAI skin testing and immunotherapy consent and instruction forms: immunotherapy administration instruction form, which can be found at http://www.aaaai.org). Build-up phase for weekly or biweekly injections (time intervals from missed injection) Up to 7 days, continue as scheduled (ie, if on weekly build-up, then it would be up to 14 days after administered injection or 7 days after the missed scheduled injection).

Eight to 13 days after missed scheduled injection; repeat previous dose.

Fourteen to 21 days after missed scheduled injection; reduce dose 25%.

Twenty-one to 28 days after missed scheduled injection; reduce previous dose 50%.

Then increase dose each injection visit as directed on the immunotherapy schedule until therapeutic maintenance dose is reached.

This suggested approach to modification of doses of allergen immunotherapy because of gaps between treatment during the build-up phase is not based on retrospective or prospective published evidence, but it is presented as a sample for your consideration. The individual physician should use this or a similar protocol as a standard operating procedure for the specific clinical setting. A similar dose reduction protocol should be developed for gaps in maintenance immunotherapy.

Linda Cox, MD et al Allergen immunotherapy: A practice parameter second update.The Journal of Allergy and Clinical ImmunologyVolume 120, Issue 3, Supplement , Pages S25-S85, September 2007.

Sincerely,
Phil Lieberman, M.D.

Key Words: immunotherapy, dosage adjustments, maintenance dose, missed injections

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